



UNITED STATES PATENT AND TRADEMARK OFFICE

cl

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,548	10/14/2003	Jeffrey S. Bauer	6122-66637	3478

24197 7590 03/07/2007
KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
----------	--------------

1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/686,548

Applicant(s)

BAUER ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 31, 35-38, 40-45, 47, 49 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 31, 35-38, 40-45, 47, 49 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed December 8, 2006 is acknowledged and has been entered.

Obvious-type Double Patenting Rejection

The obvious-type Double Patenting rejection of claims 1-4, 10-1, 31, 35-38, 40-45, 47 and 49 has been withdrawn. Applicant's amendment to the claim to include the limitation "wherein the bibulous substrate selectively delays migration of the detectable tracer" has necessitated the withdrawal.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21, 31, 35-38, 40-45, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification on page 20, lines 26-28 discloses that the sample and A-L-T conjugate can be designed to migrate at different rates through the porous strip, to allow any analyte in the sample to reach the primary capture line before the A-L-T conjugate. The specification on page 21, lines 3-5 discloses that the tracer molecule can be selected (based on size, polarity, charge, or other such characteristics) to provide specific migration characteristics. The

specification on page 24, lines 22-31 discloses that the delay in the analyte-tracer conjugate contact with the first capture area can be achieved by the arrangement of the analyte-tracer conjugate on the test strip. The disclosure teaches the selection of tracer molecules and the arrangement of tracer molecules on the substrate. The applicant does not disclose the bibulous substrate selectively delays migration of the detectable tracer. There is no description in the specification disclosing the bibulous substrate selectively delays migration of the detectable tracer.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21, 31, 35-38, 40-45, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 the recitation "selectively delays migration of the detectable tracer" is vague and indefinite. It is unclear how the bibulous substrate selectively delays migration. Does the substrate have a barrier which the detectable tracer can only penetrate after an elapsed time. Does the substrate somehow communicate with the detectable tracer? Does the substrate somehow differentiate the tracer from the analyte? There is no definition or guidance provided for the phrase in the specification and it is unclear what applicant is trying to encompass.

Claim 5, line 2 the recitation "sufficiently small" is vague and indefinite. It is unclear what is considered to be sufficiently small. There is no definition provided for the term in the specification and it is unclear what applicant intends.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 12, 13, 20, 21, 31, 35, 36, 40, 41, 45 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer et al (W0/98/39657).

Boehringer et al disclose a device and method for determining an analyte of interest. Boehringer et al disclose the device comprises a sample receiving zone (sample application area); a labeling zone (mobilization zone); and primary and secondary capture zone (Figure 1). Boehringer et al disclose that the labeling zone can comprise a labeled analyte analog. Boehringer et al disclose that the capture zones comprise an immobilized specific binding pair member. Boehringer et al disclose that the analyte and labeled analyte analog (tracer molecule) compete for binding to the immobilized binding pair member. Boehringer et al also disclose that the sample flows sequentially past the capture zones (p. 16, lines 9-38). Boehringer et al disclose the flow matrix can be bibulous (p.16 & 31) and that the labeling zone (mobilization zone) is part of the matrix (p.4). Boehringer et al disclose that the pore size of the bibulous membrane is 1 to 20 microns (1000 to 20000 nm) (p. 32). Boehringer et al discloses that the can also comprise microparticles coated with BSA (p. 42-43). Boehringer et al disclose that the sample can be saliva (p. 7). Boehringer et al also disclose that the

Art Unit: 1641

device and components can be packaged in the form of a kit and that the kit can also contain instructions for performing the methods and interpreting the results (p. 36, lines

With respect to the recitation "wherein the bibulous substrate selectively delays migration of the detectable tracer so that the analyte migrates ahead of the detectable tracer". Since Boehringer et al teaches the same structures in the same order and also teaches the same reagents as recited by applicant it is inherent that the substrate of Boehringer et al would selectively delay migration of the detectable tracer.

With respect to claim 2 as recited. Since Boehringer et al disclose the detectable tracer located in the same position as recited by applicant and since as stated above Boehringer et al disclose the same structures and same reagents as applicant has recited then Boehringer selectively delay migration of the detectable tracer so that the detectable tracer reaches the primary capture area after the analyte reaches the primary capture area.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1641

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 3-5, 8-10 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Attridge (US 5,631,170).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the detectable tracer is a delayed release detectable tracer.

Attridge discloses competition assays in which a labeled amount of analog is provided as an ancillary reagent (col 5 – col 6). Attridge discloses that this ancillary reagent is contained within a dissoluble layer (mobilization layer) (col 7, lines 4-14) which comprises a capping reagent layer which delays the dissolution of the reagent. Attridge discloses that this delayed release provides for an ideal opportunity to measure a reference signal and provides for more accurate referencing. Attridge discloses that this ancillary reagent can be used in devices such as test strips (col 5, lines 28-30).

Art Unit: 1641

Attridge disclose that the capping reagent can be polyvinyl alcohol (PVA) or sucrose (col 7 & col 13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate capping layers on the labeling zone (mobilization zone) of the test strip of Boehringer et al because Attridge teaches that these capping layers which delays the dissolution of reagent provides for an ideal opportunity to measure a reference signal and provides for more accurate referencing. And further because Attridge discloses methods can be used in devices such as test strips. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success incorporating capping layers as taught by Attridge into the test strips and methods of Boehringer et al.

With respect to the percentages of the reagent as recited in claim 10, the optimum percentage of the reagent can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Art Unit: 1641

11. Claims 6, 11 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Fredrickson (US 6,001,658) or Schram (US 5,281,539).

See above for the teachings Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to specifically teach the detectable tracer is positioned beneath the surface of the test strip.

Frederickson teaches detectable tracer impregnated (defined in Webster's as to permeate, permeate is also defined in Webster's as to penetrate or pass through) in a mobilization zone. Frederickson also teaches that the mobilization zone is located beneath the sample application zone. Therefore, Frederickson teaches that the tracer is beneath the surface of the test strip and also teaches the mobilization zone beneath the sample application zone. Frederickson teaches that this provides for a rapid, volume, timing and temperature independent visually read test strip.

Schramm teaches the impregnation of conjugates into test strips and teaches that this provides easy migration with a water front (col 5).

Further, the impregnation of labeled reagents within test strips is known in the art see also Bogema (US 6,248,598) (col 4, lines 50-56) and Bausback (US 6,335,205) (col 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to impregnate the detectable tracer of Boehringer et al as taught by Frederickson into the device and methods of Boehringer et al because Frederickson

Art Unit: 1641

teaches that this provides for a rapid, volume, timing and temperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is well known in the art and would have been obvious because it appears to be functionally equivalent. Therefore, one of ordinary skill in the art would have a reasonable expectation of success impregnating the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to impregnate the detectable tracer of Boehringer et al as taught by Schramm into the modified device and methods of Boehringer et al because Schramm teaches that it is known in the art to impregnate test strips and also teaches that this provides for easy migration with a water front. Therefore, one of ordinary skill in the art would have a reasonable expectation of success impregnating the detectable tracer of Boehringer et al.

12. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Leuving (US 4,313,734).

See above for teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to specifically state that the detectable tracer comprises a visually detectable label covalently attached to analyte or an analyte analog.

Leuving disclose particles (detectable tracer) coupled to reactive components. Leuving disclose that the components can be coupled to the particles by covalent bonds (col 2). Leuving disclose that these particles carry a charge (col 3) and that the

Art Unit: 1641

particles can be combined with other reagents. Leuving disclose that these particles can be visually detected (col 5). Leuving disclose that the particles can be 100 nm (size which falls within the size disclosed by Applicant on page 21 of the specification). Leuving disclose that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample (col 1) and also proves to be more sensitive than known techniques (col 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate labels as taught by Leuving into the device and methods of Boehringer et al because Boehringer et al specifically teaches that labels provided in Leuving (US 4,313,734) are suitable labels for the device and methods of Boehringer (p. 34, lines 21-37) and also because Leuving teaches that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample and also proves to be more sensitive than known techniques. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating the labels of Leuving into the method and device of Boehringer et al.

With respect to claim 7 since the combination of Boehringer et al and Leuving disclose the same device and reagents as recited in the instant claims one of ordinary skill in the art would expect the detectable tracer to have a retarded migration rate

Art Unit: 1641

relative to the migration of the analyte and to also possess a polarity or charge that interacts with the bibulous substrate..

13. Claims 15, 17-19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Fitzpatrick et al (US 5,451,504).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the analytes.

Fitzpatrick et al disclose test strips, which will detect any antigen in which the appropriate reagents are used. Fitzpatrick et al disclose that the analyte can be drugs and small analytes of 100 to 1000 Daltons (col 4). Fitzpatrick et al disclose that detecting drugs or drug metabolites affects the choice of proper medical treatment and that the detection of drugs or drug metabolites in a person is also important in law enforcement.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect any analyte and incorporate the appropriate reagent such as taught by Fitzpatrick into the test strip and method of Boehringer et al because Fitzpatrick et al shows that the detection of analytes affects the choice of proper medical treatment.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Hardman et al (US 6,573,108).

See above for teachings of Boehringer et al.

Boehringer et al differs from the instant invention in failing to specifically teach the detectable tracer comprises a detectable tracer for an analyte comprising an antibody to HIV or Hepatitis.

Hardman et al teach reagents used in test strips for determining an analyte of interest. Hardman et al teaches that antibodies or antigens are used to determine the analyte of interest. Hardman et al teaches the analyte of interest can be HIV or Hepatitis antigens and that one would use antibodies specific for the antigens in testing procedures (col 5, lines 10-37). Hardman et al teaches that this provides for determining for antigens of diagnostic significance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Hardman et al into the device and methods of Boehringer et al because Boehringer et al specifically teaches the analyte can be a virus (p. 8) and Boehringer et al is generic with respect to the virus and one of ordinary skill in the art would use the appropriate reagents to determine the analyte of interest in the case HIV. Further, Hardman teaches that these reagents provide for determining antigens of interest.

15. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Thieme et al (US 5,871,905).

See above for the teachings of Boehringer et al.

Boehringer et al and Attridge differ from the instant invention in failing to teach the saliva is combined with a bile acid or bile salt.

Thieme et al disclose the use of saliva as a liquid sample in immunoassays involving lateral flow immunochromatographic devices (col 1). Thieme et al disclose that the saliva is combined with a bile salt or acid (col 3, lines 19-25). Thieme et al disclose that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample. Thieme et al also disclose that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives (col 15, lines 42-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a bile acid or bile salt in combination with the saliva as taught by Thieme et al into the method of Boehringer et al because Thieme et al shows that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a chelator such as taught by Thieme et al into the test strip and method of Boehringer et al because Thieme et al shows that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives.

Response to Arguments

16. Applicant's arguments filed 12/08/06 have been fully considered but they are not persuasive.

Applicant argues that Boehringer et al cannot be said to inherently achieve separation of the tracer and analyte before they reach the primary capture zone. Applicant states that many different factors interact to achieve the desired separation such as the size, polarity and charge of the tracer, as well as matching of the pore size to the size of the conjugate, placing the conjugate on the test strip in the presence of delayed release immobilization agent. Applicant states that separating the tracer and analyte before they reach the primary capture zone is not something that is achieved by accident or happenstance, but is instead the result of the deliberate selection of variable as outlined in applicant's specification. This is not found persuasive because the factors which applicant relies upon are not recited in the instant claims which are rejected under Boehringer et al as being anticipated by Boehringer et al (see 102 rejection above and the instantly recited claims). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Boehringer et al disclose the same structures in the same order as recited by applicant and teaches the same reagents (labeled analyte analogs & capture reagents, bibulous substrates) as disclosed by Applicant. Therefore, Applicant has not recited anything structurally different than that of the prior art and thus it is inherent Boehringer et al would selectively delay migration of the detectable tracer.

Applicant argues that the First Declaration of Buck dated May 15, 2005 succinctly demonstrated that varying even one simple parameter can eliminate the separation of the tracer and analyte before they reach the primary capture zone. Applicant states that the Declaration was submitted as evidence that Boehringer et al did not inherently anticipated the pending claims and that according to MPEP 2112, inherent disclosure by a reference requires that a certain results or characteristic must necessarily be present, and that it may not be established by probabilities or possibilities. This is not found persuasive because as stated above Applicant has not recited anything structurally different than that of the prior art and since Boehringer et al teaches the same structures in the same order and the same reagents as recited by Applicant, it is inherent that the test strip of Boehringer et al selectively delays migration of the detectable tracer.

Applicant argues that Boehringer et al does not disclose any embodiment of a lateral flow assay in which separation of analyte and tracer occur and that although the reference states in passing that the support matrix may be capable of bibulous or non-bibulous flow (page 31), every example in the cited reference is one in which the substrate is rendered non-bibulous. This is not found persuasive because Boehringer et al specifically teaches that the support matrix may be either capable of bibulous or non-bibulous lateral flow (p. 16, lines 9-26, pages 31-32). Further, even that Boehringer et al teaches that non-bibulous flow is preferred, Boehringer et al does not specifically exclude bibulous flow. In fact, as stated above Boehringer et al teaches bibulous (p. 16 and p. 31) and it is well settle that a reference must be evaluated for all disclosures not

Art Unit: 1641

just its preferred embodiments. *In re Mills*, 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

Applicants arguments directed toward amended claims 3-5 and 7-10 are moot in view of the new grounds of rejection.

Applicant argues directed toward claim 6. Applicant argues that Fredrickson does not teach the advantages as stated by Examiner. This is not found persuasive because although Fredrickson does not state that it explicitly provides these advantage, Frederickson is teaching that it provides for device that provide these advantages. Further, as stated above the impregnation of reagents and positioning of mobilization zones below a sample pad are well known in the art to test strips and would have been obvious since they appear to be functionally equivalent to the mobilization zone being distal to the sample pad. Further, the placement of conjugate pads in test strip is dependent on many factors, all of which are exhaustively discussed in the prior art, specifically Millipore Guide to developing Test strip (1996, pages 1-36) (p. 25 and 26) state that the conjugate pad, if present, must have good contact with the membrane and the absorbent pad so that there is even fluid transfer between the components. And Millipore Guide Rapid later flow test strips, (1999, pages 1-37) teaches a conjugate pad below a sample pad (p. 1) and teaches that only the analyte contained in the volume of ample that migrates ahead of and with the detector reagent can contribute to signal (p. 19).

Conclusion

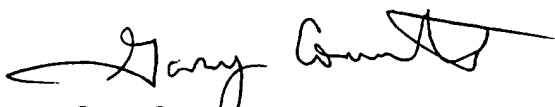
No claims are allowed.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gary Counts
Examiner
Art Unit 1641
March 1, 2007



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

02/2/07